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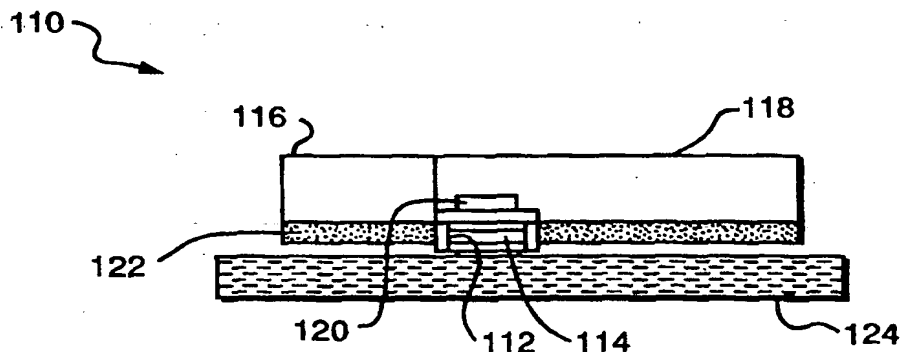
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(54) Title: SOLID STATE FLUID DELIVERY SYSTEM

(57) Abstract

An apparatus and method are disclosed that utilize piezoelectric materials as part of a delivery system capable of the rapidly repetitive dispensing of a fluid to an intended target site. In a particular embodiment, the apparatus contemplates a needleless injection system (110) which comprises a second housing structure (112), a plurality of piezoelectric elements (114) which are stacked in a layered fashion within the second housing structure, electronic circuitry

(116) disposed proximate the second housing structure and hence the layered stack of piezoelectric elements, and a first housing structure containing a fluid reservoir (118) operatively connected to the second housing structure so as to allow fluid contained within the fluid reservoir to communicate with the layered stack of piezoelectric elements. The layered stack of piezoelectric elements has at least one common aperture formed therein which extends therethrough.



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SOLID STATE FLUID DELIVERY SYSTEM

The present invention relates generally to fluid delivery systems and more particularly, to solid state delivery systems that do not require a needle-like nozzle and that utilize piezoelectric materials to achieve the rapid injection of accurate small quantities of fluid.

The delivery of fluids, including within the definition of this term liquids, solid particles and gases, in a variety of contexts has progressed in recent years to embrace various automated transport and delivery systems. Specifically, the development of equipment requiring rapid delivery of microquantities of fluid to a particular location or target, finds its application to such diverse areas as, for example, fuel delivery for internal combustion and turbine-type engines, the delivery of reagents in chemical and biological research and diagnostic procedures, and the delivery of microquantities of medicaments to patients for therapeutic purposes. In all of these instances, the extant technology and equipment is limited in its ability to define and control parameters for the precise delivery of exceedingly small volumes of liquid in rapid repeatable fashion. The problems and corresponding needs for improved equipment are particularly acute in the area of medicament delivery, as described in greater detail below.

Medications are injected through the skin to provide therapeutic effects which are more efficient or unobtainable through other drug delivery routes. Some reasons for injecting medications are: (1) chemical destruction of the medication by the gastrointestinal tract; (2) poor absorption; (3) patient too sick or too young to take the medicine orally; and (4) need for rapid action of the drug.

The most commonly used device to inject a medication is a hypodermic needle attached to a plunger syringe. These syringes come in a variety of sizes and can be automated by connecting them to a pump mechanism, or a pump designed for injection can be utilized. Such pumps are used primarily for intravascular or intrathecal delivery.

A number of needleless injection systems presently exist. These systems use a compressed gas, either CO₂ or compressed air. The gas is released at high pressure

1 on demand and acts on a movable piston which forces medication out of the nozzle
2 of the syringe. The resulting high velocity jet stream deposits the medication under
3 the skin of a patient. All needleless injection systems have the advantage of not
4 requiring "sharps" which are considered a bio-hazard and require careful disposal.

5 Present needleless injection systems are generally large and noisy. They
6 require either the cocking of a spring mechanism or an attachment to a CO₂ source.
7 Use of these devices requires a trained, skilled operator. Also, they must be
8 disassembled to be cleaned. Further more, they cannot be programmed for
9 automated delivery.

10 Certain devices that assist in the administration of medication and which
11 utilize piezoelectric materials for performing certain administration functions have
12 been described. For example, U.S. Patent Nos. 4,787,888 to Fox, 5,094,594 to
13 Brennan, 5,415,629 to Henley, and 5,007,438 to Trachibana et al are all directed
14 toward the administration of medications and/or the use of piezoelectric materials
15 for such administration or otherwise.

16 More particularly, U.S. Patent No. 4,787,888 to Fox discloses a bandage
17 assembly for percutaneous administration of medication wherein a piezoelectric
18 material is utilized so as to generate sonic vibrations for assisting the medication to
19 be absorbed through the skin of a patient. It should be noted that this patent fails
20 to disclose the use of piezoelectric materials as injection means wherein medication
21 is forcibly introduced through the skin of a patient.

22 U.S. Patent No. 5,094,594 to Brennan discloses a piezoelectric pumping
23 device wherein piezoelectric material is utilized as a pumping means in conjunction
24 with an electrophoretic unit. The Brennan apparatus is complex and cumbersome,
25 and lacks the applicability to a needleless medicament injection system, and
26 particularly such a system as is capable for forcibly introducing medication through
27 the skin of a patient.

28 U.S. Patent No. 5,415,629 to Henley discloses a programmable apparatus for
29 the transdermal delivery of medication wherein piezoelectric elements are utilized
30 for providing ultrasonic vibrations which enhance penetration of the medication

1 through the skin of a patient. It should be noted that this patent fails to disclose the
2 use of piezoelectric materials as injection means wherein medication is forcibly
3 introduced through the skin of a patient.

4 U.S. Patent No. 5,007,438 to Tachibana et al disclose an endermic
5 application kit for external medicines wherein an ultrasonic oscillation is utilized to
6 enhance the absorption of medication by the skin of a patient. It should be noted
7 that this patent fails to disclose the use of piezoelectric materials as injection means
8 wherein medication is forcibly introduced through the skin of a patient. In fact,
9 this patent fails to disclose the use of piezoelectric materials in any manner.

10 Although the above-mentioned patents are generally directed toward the
11 metered delivery of fluids, including in some instances, medications, and illustrate
12 prior applications of piezoelectric materials for their specific objectives, none are
13 directed toward providing a method for utilizing piezoelectric materials as injection
14 means wherein medication is forcibly introduced through the skin of a patient.
15 Such a method would realize all of the benefits of a needleless injection system
16 along with many other advantages as detailed below.

17 More generally, the development of a simple and inexpensive delivery
18 system that can transfer small amounts of fluid on a rapid, quiet, and repeatable
19 basis would be highly valued not only in regard to the injection of medicaments,
20 but in the other commercial and industrial areas listed above where similar needs
21 exist. Accordingly, it is toward the fulfillment of the needs expressed above that
22 the present invention is directed.

23 In its broadest aspect the present invention extends to an apparatus and
24 corresponding method for the rapid delivery of a fluid. The apparatus of the
25 invention in one aspect comprises a fluid storing component comprising at least one
26 housing having walls defining a dispensing chamber, that may be of adjustable size
27 for containing the fluid to be dispensed, at least one nozzle element defined in at
28 least one of said walls for the discharge therethrough of said fluid, and a second
29 housing which, in one embodiment, may be adapted for detachable association to
30 said first housing, including pump means for receiving and forcing a predetermined

1 volume of said fluid out of said dispensing chamber and through said nozzle
2 element toward said target. The pump means comprises at least one piezoelectric
3 element adapted to cooperate with said at least one housing to impose a
4 predetermined pressure within said dispensing chamber to force the predetermined
5 volume of said fluid through the nozzle element and to delivery said fluid to the
6 intended target.

7 An actuator for the excitation of the piezoelectric elements is included,
8 which may include means for controlling the amount and temporal schedule for
9 dispensing of said fluid. For example, the actuator of the invention may include a
10 battery unit for portable application of the apparatus, and circuitry including a
11 programmable controller for pre-setting the amount, frequency and duration of
12 fluid dispensing. This capability has particular value in the instance where the
13 inventive apparatus is applied to the administration of medication, whether in a
14 clinical setting or in a constant and personal setting. In a preferred embodiment,
15 the pump means comprises a plurality of piezoelectric elements in a stacked
16 relationship, and adapted for sequential excitation to simulate a peristaltic motion,
17 to receive a predetermined quantity of the fluid to be dispensed and thereafter to
18 eject the fluid toward the intended target.

19 The invention also extends to a method for utilizing piezoelectric materials
20 as a pump means as described above, wherein the excitation of the piezoelectric
21 element forces the fluid to egress the dispensing chamber and delivers the fluid to its
22 intended target. More particularly, the method comprises the sequential excitation
23 of plural piezoelectric elements, each associated with respective fluid chambers that
24 are in communication with each other, to convey a predetermined amount of fluid
25 from a reservoir to the chamber from which the fluid is finally dispensed to its
26 intended delivery site. Alternatively, when plural piezoelectric elements are
27 disposed in stacked adjacent relationship, the sequential excitation first defines a
28 chamber that receives a predetermined volume of the fluid, and thereafter, ejects the
29 fluid from the chamber by the rapid reduction in chamber volume. The

1 application of this sequential arrangement facilitates both speed and accuracy, as
2 precise metering and rapidly repeatable delivery are enabled.

3 In a preferred embodiment the invention comprises an apparatus for the
4 rapid and accurate delivery of medical reagents and medicaments, and particularly
5 extends to a needleless injection system which is capable of forcibly delivering
6 medication transdermally to a patient. A particular apparatus comprises a solid
7 state needleless injection system which comprises a first housing having walls
8 defining a dispensing chamber, a valve assembly comprising a cooperating valve
9 stop and valve seat formed in said first housing and located in fluid communication
10 with said dispensing chamber, and a fluid reservoir operatively connected to the
11 first housing; and a second housing defining walls one of which is in
12 communication with said first housing, which second housing contains at least one
13 piezoelectric element adapted to communicate with the first housing to dispense the
14 fluid from the system. In a particular embodiment, the first and second housings
15 define common walls that may be detachably attached to each other, and an
16 additional piezoelectric element is contained within the second housing and is
17 positioned for operative communication with the valve assembly located in the
18 second housing, to alternately permit and prevent fluid from entering said
19 dispensing chamber from said fluid reservoir.

20 The fluid reservoir provides fluid medication to the dispensing chamber
21 through the valve assembly and the fluid medication is forced out of the dispensing
22 chamber through one or more injection ports upon actuation of the piezoelectric
23 actuator associated with the dispensing chamber. The piezoelectric actuator
24 interacts with the dispensing chamber by impacting the wall of the first housing
25 that is contiguous thereto, in such a manner that the overall capacity of the
26 dispensing chamber may be altered by altering the degree of actuation of the
27 piezoelectric actuator. Thus, the piezoelectric actuator acts as a driver which forces
28 the fluid medication out of the dispensing chamber whereby it is forcibly
29 introduced through the skin of a patient.

1 The valve assembly comprises a valve stop that is preferably formed in the
2 portion of the wall of the first housing that is proximate the valve seat, and as stated
3 above, a second piezoelectric element is preferably contained within the first
4 housing for controlling the position of the valve stop within the valve seat and
5 hence the fluid flow between the fluid reservoir and the dispensing chamber.

6 The apparatus of the present invention may be constructed as a portable
7 unit using battery operation, in the instance where it is used for the delivery of
8 medication to an ambulatory individual. Further, the first housing including the
9 fluid reservoir and the dispensing chamber may be fabricated as a unit that is
10 adapted to be detached from the second housing. In a further embodiment, the
11 second housing may be discarded after all of the fluid is expelled. The apparatus
12 may also include programming capability, so that an extended schedule of delivery
13 can be preset, and sufficient medication supplied, to reduce periodic inspection of
14 the device and replenishment of the medicament.

15 The present invention broadly covers the fabrication of layered piezoelectric
16 materials and their sequential excitation to function as a "peristaltic-like" pump, to
17 rhythmically draw forward and segregate a predetermined volume of fluid, and
18 thereafter expel said fluid, wherein each of these steps can occur in rapid and
19 continuous sequence, to deliver precise and equal volumes of the fluid at a high rate
20 of frequency for an extended period of time, likewise within the control of the
21 operator.

22 A particular advantageous application of the inventive pump construction
23 and apparatus is found in its use as a needleless injection means for the delivery of a
24 fluid medication as by forcible introduction through the skin of a patient. The
25 pump means may therefore comprise at least two piezoelectric elements disposed in
26 stacked arrangement, with at least one opening journaled through adjacent layers.
27 The size of the opening may be adjusted in use in response to excitation or
28 relaxation of the piezoelectric element or elements. It can thereby be appreciated
29 that the sequential excitation of the piezoelectric elements as described herein, can
30 first define a chamber for the reception of a quantity of the fluid to be dispensed,

1 and can thereafter contract the defined volume of such chamber to eject the fluid
2 toward the intended target.

3 An actuator for the excitation of the piezoelectric elements is included,
4 which may include means for controlling the amount and temporal schedule for
5 dispensing of said fluid. For example, the actuator of the invention may include a
6 battery unit for portable application of the apparatus, and circuitry including a
7 programmable controller for pre-setting the amount, frequency and duration of
8 fluid dispensing. This capability has particular value in the instance where the
9 inventive apparatus is applied to the administration of medication, whether in a
10 clinical setting or in a constant and personal setting.

11 In another preferred embodiment, the invention comprises an apparatus for
12 the rapid and accurate delivery of medical reagents and medicaments, and
13 particularly extends to a needleless injection system which is capable of forcibly
14 delivering medication transdermally to a patient. A particular apparatus comprises
15 a needleless injection system comprising a fluid container component comprising a
16 first housing defining a dispensing chamber and including at least one nozzle
17 element, and a second fluid dispensing component comprising a plurality of
18 piezoelectric elements which are stacked in a layered fashion within the housing,
19 and an actuator means including electronic circuitry and in the instance of a
20 portable unit, a battery, which may be disposed proximate to the piezoelectric
21 elements. More particularly, the first housing may comprise a fluid reservoir
22 operatively connected to the second housing so as to interface with the layered
23 stack of piezoelectric elements. The above-stated components may be modular in
24 construction, to allow for the repeated use of the fluid dispensing component
25 containing the piezoelectric elements and the electronic circuitry, and the disposal
26 of the first housing or fluid container component. The first and second housings
27 would accordingly be detachably attached to each other and may, as a unit, be
28 releasably affixed to a surface that is to receive the fluid to be dispensed, as in the
29 instance of the removable attachment to a patient.

1 As stated above, the layered stack of piezoelectric elements has at least one
2 common aperture formed therein which extends therethrough. Each aperture may
3 be opened and closed in each piezoelectric element relative to the degree of
4 excitation applied, by the electronic circuitry, to each piezoelectric element. Thus,
5 the size of each aperture in each piezoelectric element may be individually
6 controlled by the electronic circuitry so as to allow fluid medication from the fluid
7 reservoir to be either present or absent from the aperture area. Consequently, the
8 layered stack of piezoelectric elements may be utilized as a pump wherein fluid
9 medication from the fluid reservoir is forced into and out from each aperture in
10 each piezoelectric element in the layered stack and then forcibly introduced
11 through the skin of a patient. During this pump action, the apertures act as sealed
12 dispensing chambers where fluid medication is temporarily stored as it flows
13 through the layered stack of piezoelectric elements.

14 As noted supra, the apparatus of the present invention may be constructed
15 as a portable unit with battery operation, in the instance where it is used for the
16 delivery of medication to an ambulatory individual. Further, the housing including
17 the fluid container may be fabricated either as an integral unit with the fluid
18 dispensing component unit that may be discarded in its entirety, or as a modular
19 construction wherein it is adapted to be detached from the second fluid dispensing
20 component either for refilling or disposal.

21 The use of piezoelectric actuation to mechanically force the discrete volume
22 of fluid rapidly and at high pressure, together with the simplified construction of
23 the apparatus makes the manufacture and use of the present apparatus particularly
24 attractive, and further augments the advantages thereof. For example, medications
25 dispensed with the present apparatus may be delivered in small doses within short
26 time intervals, and may thereby provide a more precise administration of a
27 medication.

28 Accordingly, a principal object of the present invention is to provide a
29 method and apparatus for the rapid and efficient delivery of fluids to target
30 destinations, that are simple and economical to manufacture and use.

1 It is a further object of the present invention to provide an apparatus as
2 aforesaid, that utilizes piezoelectric materials as a pump or injection means capable
3 of forcibly delivering the fluid to the target destination.

4 It is a still further object of the present invention to provide an injection
5 system that utilizes the properties of piezoelectric materials to respond rapidly to
6 applied potentials, and to apply them as valves and powerful pumps and to assemble
7 them as a unit.

8 Another object of the present invention is to provide a needleless, quiet,
9 compact, inexpensive, easy-to-use, battery operated injection system, that is useful
10 for the delivery of medication to a patient.

11 Another object of the present invention is to reduce medication delivery
12 pain by many small low volume injections.

13 Another object of the present invention is to reduce the skill required by an
14 operator of an injection system, and allow self-medication injection, or medication
15 injection by persons not specially trained.

16 Another object of the present invention is to provide an injection system
17 which would allow medications which are given orally, rectally, or by other means
18 for convenient home delivery to be delivered comfortably, and to provide all the
19 benefits of transcutaneous drug delivery.

20 Another object of the present invention is to have programmability, and the
21 possibility of continuous, or predetermined interval, medication delivery by an
22 attached system.

23 Other objects and advantages of the present invention will become apparent
24 to those skilled in the art from a review of the following detailed description and
25 claims, in conjunction with the accompanying drawings which are appended
26 thereto.

27 In order to facilitate a fuller understanding of the present invention,
28 reference is now made to the appended drawings. The drawings should not be
29 construed as limiting the present invention, but are intended to be exemplary only.

1 Figure 1 is a functional block diagram of a solid state fluid delivery system
2 according to a particular embodiment of the present invention;

3 Figure 2 is a functional block diagram of the delivery system shown in
4 Figure 1 with an alternate fluid reservoir;

5 Figure 3 is a functional block diagram of the delivery system shown in
6 Figure 2 with an alternate second housing structure;

7 Figure 4 is a cross-sectional view of a needleless injection system according
8 to the present invention.

9 Figure 5 is a cross-sectional view of some of the components of the
10 needleless injection system shown in Figure 4 along with another type of fluid
11 reservoir and Figure 5a is a detailed view of the layered stack of piezoelectric
12 elements.

13 Figure 6 is a close-up cross-sectional view of a common aperture in the
14 layered stack of piezoelectric elements according to the present invention, along
15 with a functional representation of a fluid reservoir.

16 Figures 7a-7d are enlarged cross-sectional views showing the sequence of
17 operation of a needleless injection system according to the present invention.

18 In its broadest aspect, the present invention relates to a delivery system for
19 fluids, including powders, liquids and gases, that is capable of rapidly repetitive
20 discharge of a precise and minute amount of such fluid on a continuous basis. Such
21 a system finds particular application in a variety of contemporary industrial
22 settings, extending from machinery design and operation, to medical devices for the
23 administration of reagents and medications.

24 Accordingly, the apparatus of the invention comprises: at least one first
25 housing having walls defining a dispensing chamber of adjustable volume for said
26 fluid, and at least one nozzle element defined in one of said walls for the discharge
27 of said fluid; at least one second housing which may be adapted, in one
28 embodiment, for detachable association with said first housing, including pump
29 means comprising at least one piezoelectric element for forcing a predetermined
30 quantity of said fluid out of said dispensing chamber and through said at least one

1 nozzle element; and actuation means including controller means for exciting said
2 pump means to force said fluid out of said dispensing chamber, and for controlling
3 the operation of said pump means.

4 A particular embodiment of the contemplated apparatus is illustrated herein
5 in relation to an apparatus for the needleless delivery of medication, and the
6 following description is presented in detailed exposition of that application and
7 embodiment. It is to be understood, however, that the features and principles of
8 the invention extend beyond the following non-limiting illustration.

9 Referring to the figures wherein like numerals designate like parts, and
10 particularly to Figure 1, there is shown a solid state needleless injection system 10
11 according to the present invention that utilizes piezoelectric materials so as to
12 provide a force that is capable of injecting matter contained within a dispensing
13 chamber through the skin of a patient. The solid state needleless injection system
14 10 comprises a second housing structure 12 containing a first piezoelectric element
15 14 and a second piezoelectric element 16, both elements 14 and 16 functioning as
16 actuators of pumping movement; and a first housing structure 18 defining a
17 dispensing chamber 20 of adjustable volume. Such volume adjustment may be
18 accomplished by means of a deformable wall 24 which may be a flexible membrane,
19 or by the disposition within chamber 20 of a wall having inward spring bias, such
20 as that illustrated with reference to fluid reservoir 26, described below.
21 Accordingly, the invention should not be limited to the specific adjustment
22 capability and means illustrated herein.

23 Housing 18 includes a valve assembly comprising a valve seat 22, and a fluid
24 reservoir 26 operatively connected to housing 18. The dispensing chamber 20, and
25 hence the second housing structure 18, has at least one injection port 28 formed
26 therein near the bottom thereof. The valve assembly also includes a valve stop 30
27 associated with deformable wall 24 as illustrated and located proximate to valve seat
28 22 and the second piezoelectric element 16. The fluid reservoir 26 has a plunger 32,
29 and a biasing member, such as a piezoelectric element, or a spring 34 as illustrated,

1 may be disposed therein to force fluids such as fluid medications that are contained
2 therein into housing structure 18.

3 In a particular embodiment, the solid state needleless injection system 10
4 comprises two main parts: (1) the second housing structure 12 containing the first
5 piezoelectric actuator 14 and the second piezoelectric actuator 16, which is reusable;
6 and (2) a disposable cassette-like unit comprising the first housing structure 18 as
7 described above, including fluid reservoir 26.

8 In operation, the second piezoelectric element 16, and hence the valve stop
9 30, is first retracted so as to allow fluid in the fluid reservoir 26 to flow through the
10 valve seat and into the dispensing chamber. The first piezoelectric element 14 is
11 then retracted so that the dispensing chamber 20 is totally filled. Next, the second
12 piezoelectric element 16 is excited so that the valve stop 30 seals the valve seat 22
13 thereby stopping the fluid from flowing in either direction between the fluid
14 reservoir 26 and the dispensing chamber 20. The first piezoelectric element 14 is
15 then excited so that the volume of the dispensing chamber 20 is rapidly decreased
16 and the fluid contained therein is displaced at high pressure. Thus, the fluid is
17 forced out of the dispensing chamber 20 through the injection port 28 at a pressure
18 sufficient in the instance of a medication, to penetrate the skin of a patient. This
19 cycle can be repeated at various rates, but it is preferably repeated within the 100 to
20 2000 Hz range.

21 As previously mentioned, more than one injection port 28 can be provided
22 in the dispensing chamber 20, and hence the first housing structure 18. Such would
23 allow for a more widespread injection area which would reduce discomfort and
24 irritation at an injection site. It should be noted that each injection port 28 is
25 typically 0.001 inches in diameter.

26 Both the second housing structure 12 and the first housing structure 18 may
27 be fabricated of a variety of rigid materials, such as plastic or metal. In the instance
28 where the fluid chamber 20 is compressible, a deformable wall 24 is included that
29 may be fabricated of a variety of flexible materials, such as clear silicon. It should
30 be further noted that the valve stop 30 may be separate from the wall 24.

1 Both the first piezoelectric element 14 and the second piezoelectric element
2 16 may be fabricated from a variety of piezoelectric materials, such as lead-
3 zirconate/lead titanate (PZT). It should be noted, however, that the second
4 piezoelectric actuator 16 may be replaced with a typical electromechanical actuator
5 (not shown) comprising a magnet and a coil.

6 The fluid reservoir 26 may be fabricated of a variety of materials, such as
7 plastic. Also the fluid reservoir 26 may take many different forms. For instance,
8 referring to Figure 2, there is shown a second embodiment of a solid state needleless
9 injection system 40 having a fluid reservoir 42 that may be fabricated of a
10 collapsible material. In such a case, external pressure P may be applied thereto so as
11 to force the fluid medication contained therein into the second housing structure
12 18.

13 The second housing structure 18 may also take many different forms. For
14 instance, referring to Figure 3, there is shown a third embodiment of a solid state
15 needleless injection system 50 having a first housing structure 52 that has a luer-lock
16 interface 54 formed therein for connection with the fluid reservoir 42. Such an
17 interface 54 allows for quick and easy attachment and removal of the fluid reservoir
18 42 from the first housing structure 52.

19 Throughout all of the above-described embodiments, an external electrical
20 excitation (not shown) is required for the first piezoelectric element 14, the second
21 piezoelectric element 16, and the electromechanical actuator (not shown). Such
22 external electrical excitation typically comprises a DC voltage source having
23 electrodes which are attached to the piezoelectric materials and to the coil,
24 respectively.

25 Referring to Figure 4, there is shown a solid state needleless injection system
26 110 according to another embodiment of the present invention that utilizes
27 piezoelectric materials so as to provide a force that is capable of injecting matter
28 contained within a sealed dispensing chamber through the skin of a patient. The
29 needleless injection system 110 comprises a second housing structure 112, plural
30 piezoelectric elements 114 (three illustrated herein) stacked in a layered fashion

1 within second housing structure 112, electronic circuitry 116 disposed proximate
2 second housing structure 112 and hence the layered stack of piezoelectric elements
3 114; and a first housing structure comprising a fluid reservoir 118, disposed
4 proximate to a second housing 112 and operatively connected thereto so as to allow
5 fluid medication contained with the fluid reservoir 118 to communicate with the
6 layered stack of piezoelectric elements 114. The interface 120 between the fluid
7 reservoir 118 and the second housing structure 112 as illustrated, may comprise a
8 luer-lock connector which allows for quick and easy attachment and removal of the
9 fluid reservoir 118 from housing structure 112. While the preceding description
10 relates to the use of a modular design where the fluid reservoir 118 and the second
11 housing structure 112 are separable, the economies of manufacturing cost allow for
12 the fabrication of the present apparatus as a single unit that, for example, may be
13 disposable in its entirety. Accordingly, the present invention is intended to cover
14 this variation within its scope.

15 It should be noted that the electronic circuitry 116 is provided and
16 distributed so as to allow the piezoelectric elements 114 to be individually excited,
17 typically with a steady state DC voltage. It should also be noted that although the
18 use of three piezoelectric elements 114 is illustrated, the apparatus could be operated
19 with as few as two such elements 114. Conversely, multiple units exceeding those
20 referenced or illustrated are contemplated within the scope hereof.

21 Referring further to Figure 4, an adhesive base 122 may be provided upon
22 which the second housing structure including the electronic circuitry 116 and the
23 fluid reservoir 118, and through which the first housing structure 112 and hence the
24 layered stack of piezoelectric elements 114 are mounted. The adhesive base 122
25 allows the entire needleless injection system 110 to be easily removably attached to
26 vicinity of the target for the dispensing of fluid, such as the skin 124 of a patient
27 illustrated herein. In the illustrated instance, the system 110 is constructed and
28 applied in similar fashion to a bandage or a patch.

29 Referring to Figure 5, the second housing structure 112 and the layered stack
30 of piezoelectric elements 114 are shown connected, through interface 120, to

1 another type of fluid reservoir 126. This type of fluid reservoir 126 requires
2 external pressure to be applied thereto so as to force fluid medication therefrom, as
3 compared to the fluid reservoir 118 described above which may have electronically
4 actuated means for forcing fluid medication therefrom. Naturally, the fluid
5 reservoirs illustrated herein are presented for purposes of illustration and not
6 limitation, as the invention contemplates the use of reservoirs having various
7 adaptations and means for the discharge or release of contained fluid.

8 Also shown in Figure 5 is a detailed view of the layered stack of
9 piezoelectric elements 114. From this view, it can be seen that the layered stack of
10 piezoelectric elements 114 as illustrated comprises an upper piezoelectric element
11 128, a middle piezoelectric element 130, and a lower piezoelectric element 132. As
12 discussed earlier herein, the invention contemplates the inclusion of only two
13 piezoelectric elements, in which event, for example, only upper element 128 and
14 middle element 130 would be present, and would operate as described later on
15 herein. The invention is thereby contemplated to embrace this further
16 embodiment within its scope.

17 Referring further to Figures 5 and 5a, piezoelectric elements 128, 130 and
18 132 as illustrated are secured to each other with an adhesive (not shown). Of
19 course, elements 128 may clamp together, and the invention is not limited to a
20 particular method of securement. Should an adhesive be used, such adhesive may
21 be of a type that will not allow fluid medication to seep therethrough. Also, it
22 should be noted that such an adhesive should desirably be pliable so as to allow the
23 individual piezoelectric elements 128, 130 and 132 to move relative to one another,
24 as will be described in detail below. Further, although the layered stack of
25 piezoelectric elements 114 is shown to be rectangular in shape, stack 114 may be
26 formed in a variety of shapes such as, for example, as a cylinder. Likewise, the
27 shape of the layered stack of piezoelectric elements 114 and the shape of the rigid
28 housing structure 112 may correspond so as to ensure efficient and compact
29 construction of this component of the system 110.

1 A plurality of common apertures 134 are formed in the layered stack of
2 piezoelectric elements 114. The apertures 134 are termed common because they are
3 aligned and extend down through the entire layered stack of piezoelectric elements
4 114. The diameter of each of the apertures 134 may vary, and for example, may be
5 as small as 150 micrometers. In such last-mentioned instance, the apertures 134
6 may be preferably formed using a laser.

7 Referring to Figure 6, the layered stack of piezoelectric elements 114 is
8 shown with a common aperture 134, along with a functional representation of a
9 fluid reservoir 136 and an interface 120. In this particular view, all of the
10 piezoelectric elements 128, 130 and 132 are in a dormant state (i.e. not excited).
11 Thus, the common aperture 134 has a constant diameter extending all the way
12 through the layered stack of piezoelectric elements 114.

13 Referring to Figure 7a, the lower piezoelectric element 132 is excited so as to
14 narrow its section of the common aperture 134 to about 25 microns in diameter.
15 This step allows fluid medication to enter into the aperture 134 adjacent the upper
16 piezoelectric element 128 and the middle piezoelectric element 130. In the instance
17 where lower piezoelectric element 132 is absent, the aperture 134 could be provided
18 with a constricted orifice or nozzle element that would effectively curtail
19 appreciable fluid escape and thereby confer an equivalent function and effect to that
20 of piezoelectric element 132.

21 Referring to Figure 7b, the upper piezoelectric element 128 is excited so as
22 to narrow its section of the common aperture 134. This step essentially creates a
23 sealed dispensing chamber in the aperture 134 adjacent the middle piezoelectric
24 element 130.

25 Referring to Figure 7c, the middle piezoelectric element 130 is excited so as
26 to narrow its section of the common aperture 134. This step forces the fluid
27 medication out of the sealed dispensing chamber (i.e. the second of the common
28 aperture 134 adjacent the middle piezoelectric element 130) and through the
29 aperture opening in the lower piezoelectric element 132. Since, in application, the

1 lower piezoelectric element 132 will be directly abutting the skin of a patient, the
2 fluid medication will be forcibly introduced through the skin of the patient.

3 Referring to Figure 7d, the upper piezoelectric element 128 is relaxed so as
4 to expand its section of the common aperture 134 and thereby allow the entire
5 sequential process to be repeated. Indeed, this process can be repeated until all of
6 the fluid medication is dispensed from a fluid reservoir 118, 126. This entire
7 sequential process can probably best be described as a peristaltic pumping action.

8 First housing structure 112 may be fabricated of a variety of materials, such
9 as plastic or metal, and second housing structure including fluid reservoir 118, 126
10 may be fabricated of a variety of materials, such as plastic or a collapsible material.
11 Also, fluid reservoir 118, 126 may take many different forms as indicated in Figures
12 4 and 5. Further, piezoelectric elements such as illustrative elements 128, 130, and
13 132 may be fabricated from a variety of piezoelectric materials, such as lead-
14 zirconate/lead titanate (PZT).

15 Finally, it should be noted that throughout all of the above-described
16 embodiment, electrical connections must be made between the electronic circuitry
17 116 and the individual piezoelectric elements 128, 130 and 132. This is typically
18 accomplished by providing each of the piezoelectric elements 128, 130 and 132 with
19 electrodes (not shown) and electrically connecting these electrodes to the electronic
20 circuitry 116. The electronic circuitry 116 may be somewhat sophisticated so as to
21 allow programmability, with the possibility of continuous, or predetermined
22 interval, delivery of the fluid medication.

23 Thus, the fluid medication is forced out of the dispensing chamber 120
24 through the injection port 128 at a pressure sufficient enough to penetrate the skin
25 of a patient. This cycle can be repeated at various rates, and an illustrative, non-
26 limiting range of repetition of from about 100 to about 2000 Hz range may be used.

27 As previously mentioned, more than one injection port 128 can be provided
28 in the dispensing chamber 120, and hence in the second housing structure 118.
29 Such would allow for a more widespread injection area which would reduce

1 discomfort and irritation at an injection site. An illustrative and non-limiting size
2 for an injection port 28 may be about 0.0025 cm. in diameter.

3 Throughout all of the above-described embodiments, an external electrical
4 excitation (not shown) is required for the piezoelectric elements 128, 130 and 132.
5 Such external electrical excitation typically comprises a DC voltage source having
6 electrodes which are attached to the piezoelectric materials and to the coil,
7 respectively.

8 With the present invention method now fully described, it can thus be seen
9 that the primary objective set forth above is efficiently attained, and since certain
10 changes may be made in the above-described embodiments without departing from
11 the scope of the invention, it is intended that all matter contained in the above
12 description or shown in the accompanying drawings shall be interpreted as
13 illustrative and not restrictive, the scope of the invention being defined in the
14 appended claims.

- 1 1. An apparatus for the rapid and repeatable delivery of small quantities of a
2 fluid to an intended target, comprising:
 - 3 (a) at least one first housing (18) having walls defining a dispensing
4 chamber for said fluid, and at least one nozzle element defined in one of said walls
5 for the discharge of said fluid; and
 - 6 (b) at least one second housing (12) communicating with said first
7 housing, said second housing comprising pump means comprising at least one
8 piezoelectric element (14,16) for forcing a predetermined quantity of said fluid out
9 of said dispensing chamber and through said at least one nozzle element, and
10 actuation means for exciting said pump means to force said fluid out of said
11 dispensing chamber.
- 12 2. The apparatus according to claim 1, wherein said first housing includes a
13 fluid reservoir (26) for holding the quantity of fluid to be dispensed, said fluid
14 reservoir in fluid communication with said dispensing chamber, and a valve
15 assembly (22,30) for controlling the quantity and rate of transfer of fluid from said
16 fluid reservoir to said dispensing chamber.
- 17 3. The apparatus according to claim 1, further including a secondary pump
18 means (34) associated with said fluid reservoir to place pressure on said reservoir to
19 expel fluid contained therein.
- 20 4. A solid state needleless injection system that utilizes piezoelectric
21 materials to forcibly introduce fluid medication through the skin of a patient, said
22 system comprising:
 - 23 a first housing (18), said first housing having at least one wall and
24 defining a dispensing chamber of variable volume formed therein, said dispensing
25 chamber having an output port and an opening formed therein; and
 - 26 a second housing (12) located in communication with said first
27 housing, said second housing having at least one wall and defining a first
28 piezoelectric actuator (14), said first piezoelectric actuator being disposed in
29 communication with a wall of said first housing proximate said dispensing
30 chamber, and being excitable so as to provide a driving force against said wall to

1 thereby force fluid from within said dispensing chamber through said output port
2 (28).

3 5. The system according to claim 4, and comprising at least one of the
4 following features:

5 (a) said dispensing chamber also has an input port formed therein,
6 wherein said input port allows fluid to enter into said dispensing chamber;

7 (b) said fluid reservoir has an output port formed therein, said output
8 port of said fluid reservoir is operatively connected to said input port of said
9 dispensing chamber so as to allow said fluid to flow from said fluid reservoir to said
10 dispensing chamber;

11 (c) a valve assembly (22, 30) operatively connected between said
12 output port and said fluid reservoir and said input port of said dispensing chamber
13 so as to control the flow of fluid between said fluid reservoir to said dispensing
14 chamber; and

15 (d) a valve assembly comprising:

16 a valve seat (22) formed in said first housing;

17 a valve stop (30) formed in said first housing and positioned
18 to cooperate with said valve seat to alternately permit and prevent the flow of fluid
19 from said fluid reservoir and to said dispensing chamber; and

20 an actuation means (16) for controlling the position of said
21 valve stop with respect to said valve seat.

22 6. An apparatus for the rapid and repeatable delivery of small quantities of a
23 fluid to an intended target, comprising:

24 (a) at least one first housing (118) having walls defining a dispensing
25 chamber for said fluid, and at least one nozzle element defined in one of said walls
26 for the discharge of said fluid; and

27 (b) at least one second housing (112) communicating with said first
28 housing, said second housing comprising pump means comprising a plurality of
29 piezoelectric elements (114) disposed in a stacked arrangement adjacent one
30 another, each of said piezoelectric elements having at least one opening therein, said

1 openings being journaled within each of said piezoelectric elements in axial
2 alignment as between adjacent said piezoelectric elements, said axially aligned
3 stacked piezoelectric elements being plially sealed to one another whereby to
4 define a non-porous chamber for receiving and holding a predetermined volume of
5 said fluid, said plurality of piezoelectric elements being adapted for sequential
6 excitation to simulate a peristaltic motion whereby to receive a predetermined
7 volume of said fluid from said dispensing chamber, and thereafter to eject the same
8 through said at least one nozzle element toward said target; and actuation means
9 (116) for exciting said pump means.

10 7. A needleless injection system that utilizes layered piezoelectric materials
11 to forcibly introduce fluid medication through the skin of a patient, said system
12 comprising:

13 a second housing (112) having a first opening and a second opening formed
14 therein, a plurality of piezoelectric elements (114), said plurality of piezoelectric
15 elements being stacked in a layered fashion and plially sealed to one another within
16 said second housing between said first opening and said second opening, each of said
17 plurality of piezoelectric elements having an aperture formed therein, each said
18 aperture being aligned so as to form a common aperture extending through said
19 layered stack of piezoelectric elements from said first opening to said second
20 opening whereby to define a chamber for receiving and holding a predetermined
21 volume of said fluid;

22 a first housing comprising a fluid reservoir (118), said fluid reservoir being
23 operatively connected to said first opening of said second housing so as to allow
24 fluid medication contained within said fluid reservoir to communicate with said
25 layered stack of piezoelectric elements; and

26 electronic circuitry (116), said electronic circuitry being electrically
27 connected to said layered stack of piezoelectric elements so as to allow each of said
28 plurality of piezoelectric elements to be individually excited and the size of each of
29 said aperture to be individually controlled, thereby allowing said layered stack of
30 piezoelectric elements to be utilized as a pump wherein fluid medication from said

1 fluid reservoir may be forced into and out from each said aperture and ultimately
2 be forcibly introduced through the skin of a patient.

3 8. The system according to claim 6, further comprising an interface
4 connector, preferably a luer-lock connector (120) between said fluid reservoir and
5 said first opening of said second housing.

6 9. The system according to claim 6, further comprising securement means
7 (122) upon which said electronic circuitry and said fluid reservoir and through
8 which said second housing (112) and hence said layered stack of piezoelectric
9 elements are mounted so as to allow said system to be easily removably attached to
10 a patient.

11 10. The system according claim 6, wherein each of said plurality of
12 piezoelectric elements have a plurality of apertures (134) formed therein, wherein
13 each of said plurality apertures are aligned in groups so as to form a plurality of
14 common apertures extending through said layered stack of piezoelectric elements
15 from said first opening to said second opening.

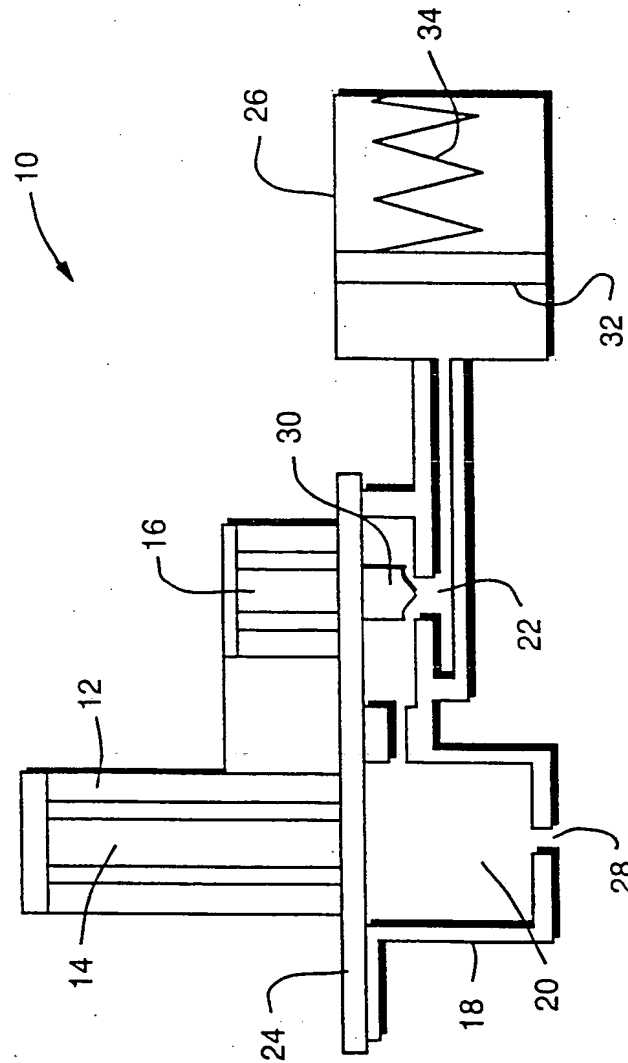


FIG. 1

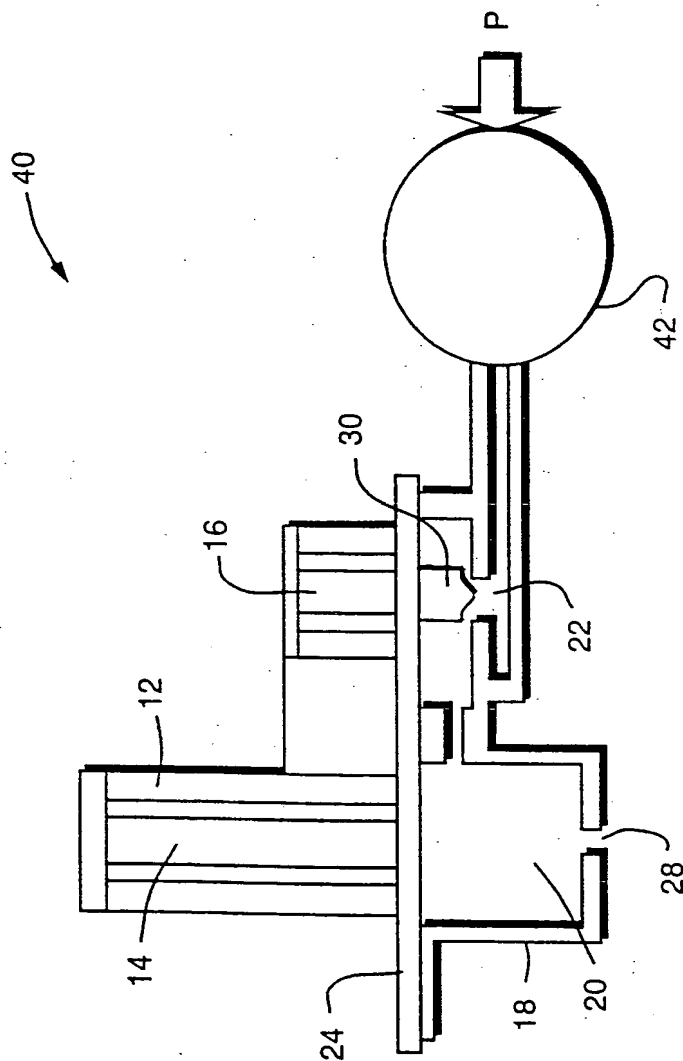


FIG. 2

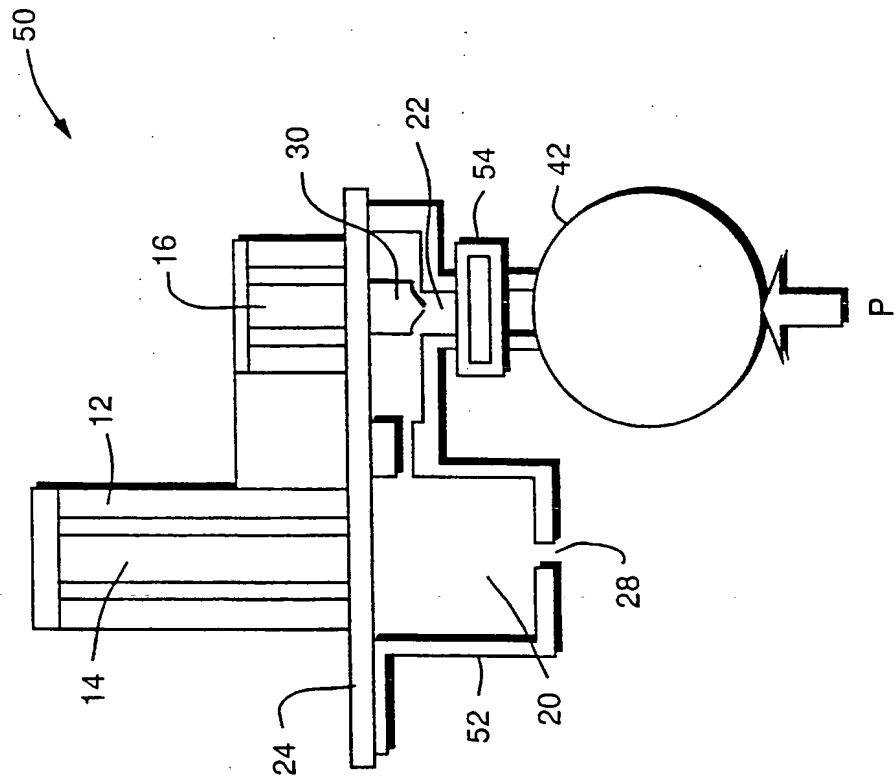


FIG. 3

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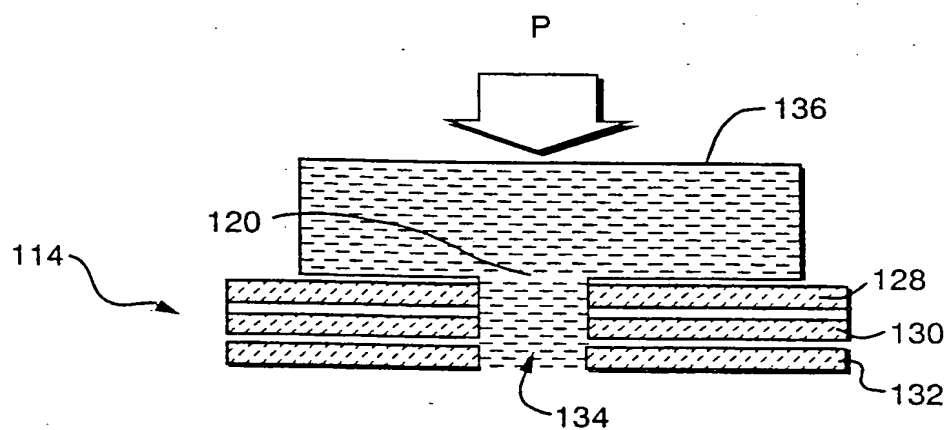


FIG. 6

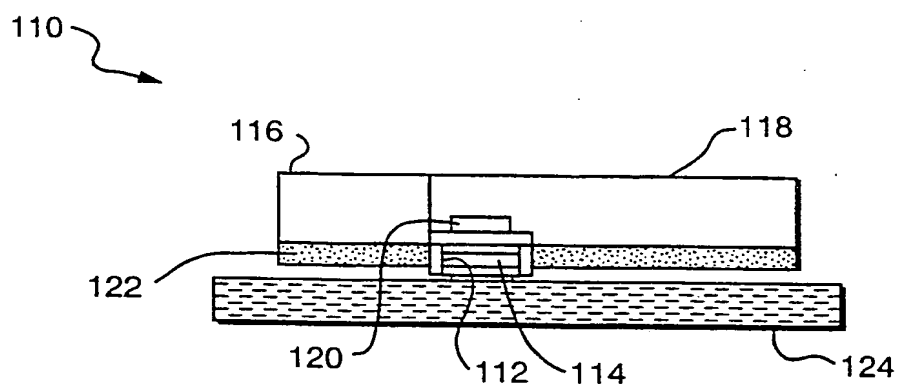
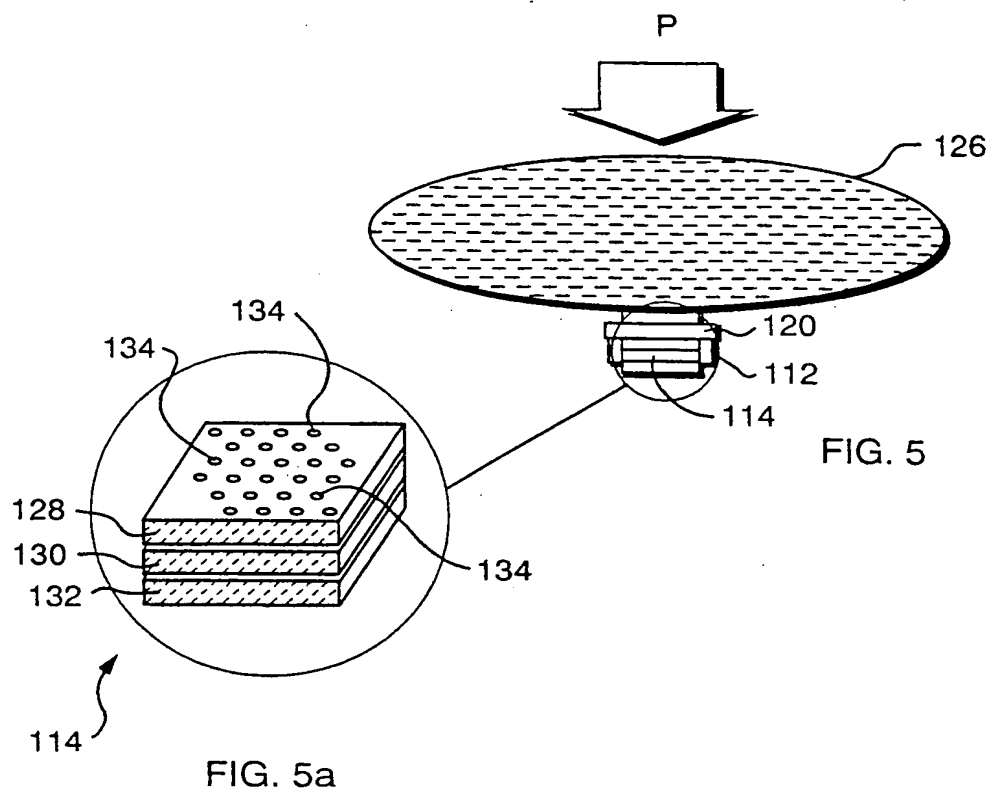


FIG. 4

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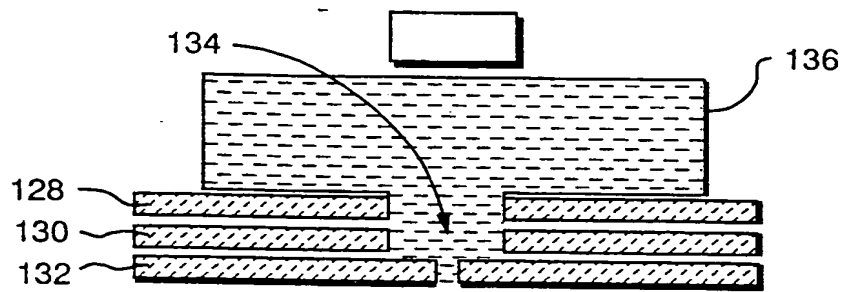


FIG. 7a

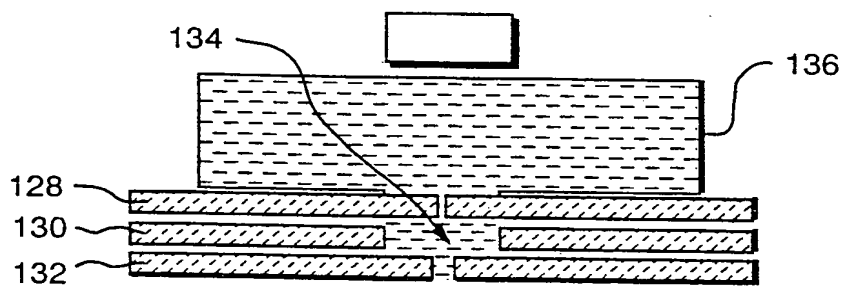


FIG. 7b

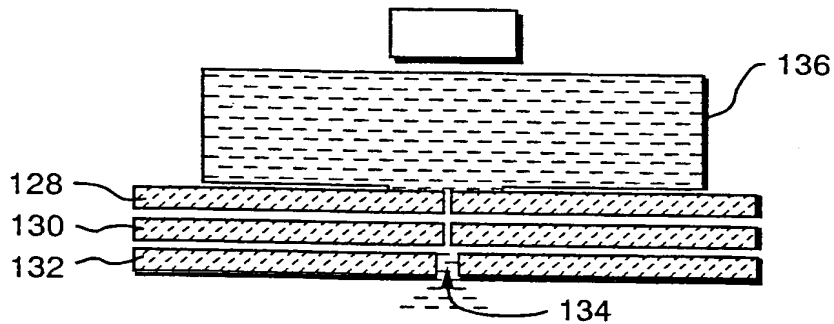


FIG. 7c

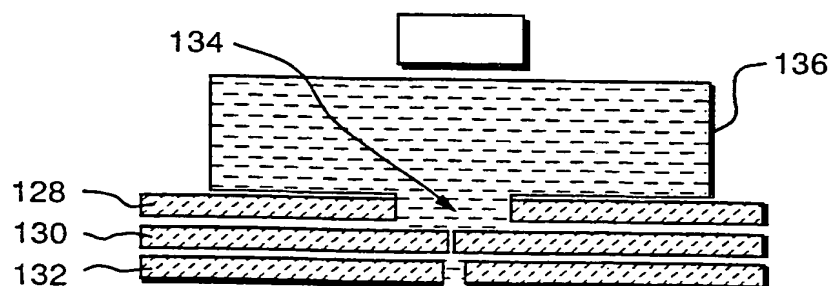


FIG. 7d

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/08903

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 13/00

US CL :604/19

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/19, 20, 82, 416, 890.1, 891.1, 892.1, 82,416

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,474,527 A (BETTINGER) 12 December 1995, entire patent.	1-10
Y	US 4,944,659 A (LABBE et al.) 31 July 1990, entire patent.	1-10

☐

Further documents are listed in the continuation of Box C.

☐

See patent family annex.

* Special categories of cited documents:	*T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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Date of the actual completion of the international search

19 AUGUST 1997

Date of mailing of the international search report

10 SEP 1997

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